



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

0721 '00 DEC 12 P2:14

DEC 11 2000

Bruce Silverglade,  
Director of Legal Affairs  
Ilene Ringel Heller,  
Senior Staff Attorney  
Center for Science in the Public Interest  
1875 Connecticut Ave., NW  
Suite 300  
Washington, D.C. 20009-5728

Re: Docket 00P-1369/CP1

Dear Mr. Silverglade and Ms. Heller:

This letter responds to your citizen petition dated June 26, 2000, requesting that the Food and Drug Administration (FDA) take prompt enforcement action against the Kellogg Company (Kellogg). In particular, your petition asks the agency to order Kellogg to remove the claim "Adequate intakes of folic acid, vitamins B6 and B12 may promote a healthy cardiovascular system" from the labels of various cereal products on the basis that this statement is an unapproved health claim.

In accordance with Title 21 of the Code of Federal Regulations (21 CFR) section 10.30(e)(3) this letter is to advise you that FDA is denying, without prejudice, your petition.

A citizen petition allows individuals to ask the agency to initiate a particular administrative action, for example, to issue, amend, or revoke a regulation or order (see 21 CFR §10.30(a) and §10.30(b)). The definition of "administrative action" for the purposes of 21 CFR Part 10 excludes the referral of apparent violations to United States attorneys for the institution of civil or criminal proceedings, and acts in preparation of a referral. Enforcement actions are solely within the discretion of the Commissioner and are not an appropriate subject of citizen petitions. Accordingly, we are denying your petition without prejudice.

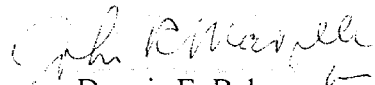
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Although the FDA is denying your petition, we can advise you that in a letter dated October 30, 2000 to Kellogg, the Office of Nutritional Products, Labeling and Dietary Supplements addressed its concerns regarding similar claims on the label of Kellogg's All-Bran cereal.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Dennis E. Baker", with a stylized flourish at the end.

Dennis E. Baker  
Associate Commissioner  
for Regulatory Affairs